

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA
MARKETING, SALES PRACTICES AND
PRODUCTS LIABILITY LITIGATION

This document relates to

JOHNNY CORNELIUS and PATRICIA
HAMMESFAHR,

Plaintiffs,

vs.

PFIZER, INC., PHARMACIA CORPORATION,
and G.D. SEARLE, LLC,

Defendants.

) MDL Docket No. 1699

) CASE NO. 3:08-cv-1797-CRB

) **PFIZER INC., PHARMACIA**
) **CORPORATION, AND G.D.**
) **SEARLE LLC'S ANSWER TO**
) **COMPLAINT**

) **JURY DEMAND ENDORSED**
) **HEREIN**

1 NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiffs' Complaint as
2 "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation ("Pharmacia"), and G.D. Searle LLC
3 (improperly captioned in Plaintiffs' Complaint as "G.D. Searle, LLC") ("Searle") (collectively
4 "Defendants"), and file this Answer to Plaintiffs' Complaint ("Complaint"), and would
5 respectfully show the Court as follows:

6 **I.**

7 **PRELIMINARY STATEMENT**

8 The Complaint does not state in sufficient detail when Plaintiffs were prescribed or used
9 Celebrex® (celecoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted
10 generally. Defendants may seek leave to amend this Answer when discovery reveals the
11 specific time periods in which Plaintiffs were prescribed and used Celebrex®.

12 **II.**

13 **ANSWER**

14 1. Defendants admit that Plaintiffs brought this civil action seeking monetary damages, but
15 deny that Plaintiffs are entitled to any relief or damages. Defendants admit that, during certain
16 periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United
17 States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in
18 accordance with their approval by the FDA. Defendants admit that, during certain periods of
19 time, Celebrex® was manufactured and packaged for Searle, which developed, tested,
20 marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by
21 healthcare providers who are by law authorized to prescribe drugs in accordance with their
22 approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used
23 in accordance with its FDA-approved prescribing information. Defendants state that the
24 potential effects of Celebrex® were and are adequately described in its FDA-approved
25 prescribing information, which was at all times adequate and comported with applicable
26 standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused
27 Plaintiffs injury or damages, and deny the remaining allegations in this paragraph of the
28 Complaint.

Response to Allegations Regarding Parties

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

3. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and citizenship, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that, as the result of a merger in April 2003, Searle became a subsidiary of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that, during certain periods of time, Pharmacia

1 marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare
2 providers who are by law authorized to prescribe drugs in accordance with their approval by the
3 FDA. Defendants state that Plaintiffs' allegations regarding "predecessors in interest" are
4 vague and ambiguous. Defendants are without knowledge or information to form a belief as to
5 the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining
6 allegations in this Paragraph of the Complaint.

7 **Response to Allegations Regarding Jurisdiction and Venue**

8 7. Defendants are without knowledge or information sufficient to form a belief as to the
9 truth of the allegations in this paragraph of the Complaint regarding Plaintiffs' citizenship and
10 the amount in controversy, and, therefore, deny the same. However, Defendants admit that
11 Plaintiffs claim that the parties are diverse and that the amount in controversy exceeds \$75,000,
12 exclusive of interests and costs.

13 8. Defendants are without knowledge or information sufficient to form a belief as to the
14 truth of the allegations in this paragraph of the Complaint regarding the judicial district in
15 which the asserted claims allegedly arose, and, therefore, deny the same. Defendants admit
16 that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted
17 Celebrex® in the United States, including California and Florida, to be prescribed by healthcare
18 providers who are by law authorized to prescribe drugs in accordance with their approval by the
19 FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and
20 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
21 Celebrex® in the United States to be prescribed by healthcare providers who are by law
22 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
23 that they provided FDA-approved prescribing information regarding Celebrex®. Defendants
24 admit that they do business in the States of California and Florida. Defendants state that
25 Plaintiffs' allegations regarding "predecessors in interest" are vague and ambiguous.
26 Defendants are without knowledge or information to form a belief as to the truth of such
27 allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny
28 committing a tort in the States of California and Florida, and deny the remaining allegations in

1 this paragraph of the Complaint.

2 **Response to Allegations Regarding Interdistrict Assignment**

3 9. Defendants state that this paragraph of the Complaint contains legal contentions to
4 which no response is required. To the extent that a response is deemed required, Defendants
5 admit that this case should be transferred to In re: Bextra and Celebrex Marketing, Sales Prac.
6 and Prods. Liab. Litig., MDL-1699, assigned to the Honorable Charles R. Breyer by the Judicial
7 Panel on Multidistrict Litigation on September 6, 2005.

8 **Response to Factual Allegations**

9 10. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
10 and co-promoted Celebrex® in the United States, including Florida, to be prescribed by
11 healthcare providers who are by law authorized to prescribe drugs in accordance with their
12 approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was
13 manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and
14 distributed Celebrex® in the United States to be prescribed by healthcare providers who are by
15 law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants
16 admit that they provided FDA-approved prescribing information regarding Celebrex®.
17 Defendants deny the remaining allegations in this paragraph of the Complaint.

18 11. Defendants are without knowledge or information sufficient to form a belief as to the
19 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
20 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
21 effective when used in accordance with its FDA-approved prescribing information. Defendants
22 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny
23 the remaining allegations in this paragraph of the Complaint.

24 12. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny

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1 the remaining allegations in this paragraph of the Complaint.

2 13. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny the remaining the allegations in this paragraph of the Complaint.

7 14. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed
8 and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who
9 are by law authorized to prescribe drugs in accordance with their approval by the FDA.
10 Defendants admit that, during certain periods of time, Celebrex® was manufactured and
11 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
12 Celebrex® in the United States to be prescribed by healthcare providers who are by law
13 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
14 that they provided FDA-approved prescribing information regarding Celebrex®. Defendants
15 deny the remaining allegations in this paragraph of the Complaint.

16 15. Defendants admit that Celebrex® is in a class of drugs that is, at times, referred to as
17 non-steroidal anti-inflammatory drugs (“NSAIDS”). Defendant states that, as stated in the
18 FDA-approved labeling for Celebrex®, “[t]he mechanism of action of Celebrex is believed to
19 be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2
20 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the
21 cyclooxygenase-1 (COX-1) isoenzyme.” Defendants admit that Celebrex® was approved by
22 the FDA on December 31, 1998. Defendant states that Celebrex® is a prescription medication
23 which is approved by the FDA for the following indications: (1) for relief of the signs and
24 symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in
25 adults; (3) for the management of acute pain in adults; (4) for the treatment of primary
26 dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial
27 adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance
28 surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the

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1 signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older.
2 Defendants deny the remaining allegations in this paragraph of the Complaint.

3 16. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining the allegations in this paragraph
8 of the Complaint.

9 17. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining the allegations in this paragraph of the Complaint.

17 18. Defendants state that Celebrex® was and is safe and effective when used in accordance
18 with its FDA-approved prescribing information. Defendants state that the potential effects of
19 Celebrex® were and are adequately described in its FDA-approved prescribing information,
20 which was at all times adequate and comported with applicable standards of care and law.
21 Defendants admit that they provided FDA-approved prescribing information regarding
22 Celebrex®. Defendants deny the remaining the allegations in this paragraph of the Complaint.

23 19. Defendants state that Celebrex® was and is safe and effective when used in accordance
24 with its FDA-approved prescribing information. Defendants state that the potential effects of
25 Celebrex® were and are adequately described in its FDA-approved prescribing information,
26 which was at all times adequate and comported with applicable standards of care and law.
27 Defendants deny any wrongful conduct and deny the remaining the allegations in this paragraph
28 of the Complaint.

20. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny the remaining the allegations in this paragraph of the Complaint.

Response to First Cause of Action: Products Liability

21. Defendants incorporate by reference their responses to each paragraph of Plaintiffs' Complaint as if fully set forth herein.

22. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs and Decedents used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs or Decedents injury or damages, and deny the remaining allegations this paragraph of the Complaint, including all subparts.

23. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and

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1 packaged for Searle, which developed, tested, marketed, co-promoted and distributed
2 Celebrex® in the United States to be prescribed by healthcare providers who are by law
3 authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit
4 that they provided FDA-approved prescribing information regarding Celebrex®. Defendants
5 deny the remaining the allegations in this paragraph of the Complaint.

6 24. Defendants admit that Celebrex® was expected to reach consumers without substantial
7 change from the time of sale. Defendants are without knowledge or information sufficient to
8 form a belief as to the truth of the allegations in this paragraph of the Complaint regarding
9 whether Plaintiffs used Celebrex®, and, therefore, deny the same. Defendants state that
10 Celebrex® was and is safe and effective when used in accordance with its FDA-approved
11 prescribing information. Defendants state that the potential effects of Celebrex® were and are
12 adequately described in its FDA-approved prescribing information, which was at all times
13 adequate and comported with applicable standards of care and law. Defendants deny any
14 wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining
15 allegations this paragraph of the Complaint.

16 25. Defendants are without knowledge or information sufficient to form a belief as to the
17 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
18 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
19 effective when used in accordance with its FDA-approved prescribing information. Defendants
20 state that the potential effects of Celebrex® were and are adequately described in its FDA-
21 approved prescribing information, which was at all times adequate and comported with
22 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
23 Celebrex® is defective or unreasonably dangerous, deny that Celebrex® caused Plaintiffs
24 injury or damages, and deny the remaining allegations this paragraph of the Complaint.

25 26. Defendants state that Celebrex® was and is safe and effective when used in accordance
26 with its FDA-approved prescribing information. Defendants state that the potential effects of
27 Celebrex® were and are adequately described in its FDA-approved prescribing information,
28 which was at all times adequate and comported with applicable standards of care and law.

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1 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
2 damages, and deny the remaining allegations this paragraph of the Complaint.

3 27. Defendants state that Celebrex® was and is safe and effective when used in accordance
4 with its FDA-approved prescribing information. Defendants state that the potential effects of
5 Celebrex® were and are adequately described in its FDA-approved prescribing information,
6 which was at all times adequate and comported with applicable standards of care and law.
7 Defendants deny any wrongful conduct and deny the remaining allegations this paragraph of
8 the Complaint.

9 28. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
16 remaining allegations this paragraph of the Complaint.

17 29. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
19 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
24 Celebrex® caused Plaintiffs injury or damages, and deny the remaining allegations this
25 paragraph of the Complaint.

26 30. Defendants state that Celebrex® was and is safe and effective when used in accordance
27 with its FDA-approved prescribing information. Defendants state that the potential effects of
28 Celebrex® were and are adequately described in its FDA-approved prescribing information,

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1 which was at all times adequate and comported with applicable standards of care and law.
2 Defendants deny any wrongful conduct and deny the remaining allegations this paragraph of
3 the Complaint.

4 31. Defendants state that Celebrex® was and is safe and effective when used in accordance
5 with its FDA-approved prescribing information. Defendants state that the potential effects of
6 Celebrex® were and are adequately described in its FDA-approved prescribing information,
7 which was at all times adequate and comported with applicable standards of care and law.
8 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
9 damages, and deny the remaining allegations this paragraph of the Complaint.

10 32. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
11 damages, and deny the remaining allegations this paragraph of the Complaint.

12 33. Defendants state that Celebrex® was and is safe and effective when used in accordance
13 with its FDA-approved prescribing information. Defendants state that the potential effects of
14 Celebrex® were and are adequately described in its FDA-approved prescribing information,
15 which was at all times adequate and comported with applicable standards of care and law.
16 Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex®
17 caused Plaintiffs injury or damages, and deny the remaining allegations this paragraph of the
18 Complaint.

19 34. Defendants are without knowledge or information sufficient to form a belief as to the
20 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
21 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
22 effective when used in accordance with its FDA-approved prescribing information. Defendants
23 deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or damages, and deny
24 the remaining allegations this paragraph of the Complaint.

25 35. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
26 damages, and deny the remaining allegations this paragraph of the Complaint.

27 **Response to Second Cause of Action: Strict Products Liability**

28 36. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'

1 Complaint as if fully set forth herein.

2 37. Defendants state that Celebrex® was and is safe and effective when used in accordance
3 with its FDA-approved prescribing information. Defendants state that the potential effects of
4 Celebrex® were and are adequately described in its FDA-approved prescribing information,
5 which was at all times adequate and comported with applicable standards of care and law.
6 Defendants deny any wrongful conduct and deny the remaining allegations this paragraph of
7 the Complaint.

8 38. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
9 damages, and deny the remaining allegations this paragraph of the Complaint.

10 39. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
11 damages, and deny the remaining allegations this paragraph of the Complaint.

12 **Response to Third Cause of Action: Express Warranty**

13 40. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
14 Complaint as if fully set forth herein.

15 41. Defendants are without knowledge or information sufficient to form a belief as to the
16 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
17 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
18 effective when used in accordance with its FDA-approved prescribing information. Defendants
19 state that the potential effects of Celebrex® were and are adequately described in its FDA-
20 approved prescribing information, which was at all times adequate and comported with
21 applicable standards of care and law. Defendants admit that they provided FDA-approved
22 prescribing information regarding Celebrex®. Defendants deny the remaining allegations this
23 paragraph of the Complaint.

24 42. Defendants are without knowledge or information sufficient to form a belief as to the
25 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
26 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
27 effective when used in accordance with its FDA-approved prescribing information. Defendants
28 state that the potential effects of Celebrex® were and are adequately described in its FDA-

1 approved prescribing information, which was at all times adequate and comported with
2 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
3 remaining allegations this paragraph of the Complaint.

4 43. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
5 damages, and deny the remaining allegations this paragraph of the Complaint.

6 **Response to Fourth Cause of Action: Implied Warranty**

7 44. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
8 Complaint as if fully set forth herein.

9 45. Defendants are without knowledge or information sufficient to form a belief as to the
10 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
11 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
12 effective when used in accordance with its FDA-approved prescribing information. Defendants
13 state that the potential effects of Celebrex® were and are adequately described in its FDA-
14 approved prescribing information, which was at all times adequate and comported with
15 applicable standards of care and law. Defendants deny any wrongful conduct, deny that
16 Celebrex® is defective, and deny the remaining allegations this paragraph of the Complaint.

17 46. Defendants are without knowledge or information sufficient to form a belief as to the
18 truth of the allegations in this paragraph of the Complaint regarding whether Plaintiffs used
19 Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and
20 effective when used in accordance with its FDA-approved prescribing information. Defendants
21 state that the potential effects of Celebrex® were and are adequately described in its FDA-
22 approved prescribing information, which was at all times adequate and comported with
23 applicable standards of care and law. Defendants deny any wrongful conduct and deny the
24 remaining allegations this paragraph of the Complaint.

25 47. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
26 damages, and deny the remaining allegations this paragraph of the Complaint.

27 **Response to Fifth Cause of Action: Unjust Enrichment**

28 48. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'

1 Complaint as if fully set forth herein.

2 49. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
3 damages, and deny the remaining allegations this paragraph of the Complaint.

4 **Response to Allegations Regarding Damages**

5 50. Defendants incorporate by reference their responses to each paragraph of Plaintiffs'
6 Complaint as if fully set forth herein.

7 51. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
8 damages, and deny the remaining allegations this paragraph of the Complaint, including all
9 subparts.

10 52. Answering the unnumbered paragraph following Paragraph 51 of the Complaint,
11 Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiffs injury or
12 damages, and deny the remaining allegations this paragraph of the Complaint, including all
13 subparts.

14 **III.**

15 **GENERAL DENIAL**

16 Defendants deny all allegations and/or legal conclusions set forth in Plaintiffs'
17 Complaint that have not been previously admitted, denied, or explained.

18 **IV.**

19 **AFFIRMATIVE DEFENSES**

20 Defendants reserve the right to rely upon any of the following or additional defenses to
21 claims asserted by Plaintiffs to the extent that such defenses are supported by information
22 developed through discovery or evidence at trial. Defendants affirmatively show that:

23 **First Defense**

24 1. The Complaint fails to state a claim upon which relief can be granted.

25 **Second Defense**

26 2. Celebrex® is a prescription medical product. The federal government has preempted
27 the field of law applicable to the labeling and warning of prescription medical products.
28 Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable

1 federal law. Plaintiffs' causes of action against Defendants, therefore, fail to state a claim upon
2 which relief can be granted; such claims, if allowed, would conflict with applicable federal law
3 and violate the Supremacy Clause of the United States Constitution.

4 **Third Defense**

5 3. At all relevant times, Defendants provided proper warnings, information and
6 instructions for the drug in accordance with generally recognized and prevailing standards in
7 existence at the time.

8 **Fourth Defense**

9 4. At all relevant times, Defendants' warnings and instructions with respect to the use of
10 Celebrex® conformed to the generally recognized, reasonably available, and reliable state of
11 knowledge at the time the drug was manufactured, marketed and distributed.

12 **Fifth Defense**

13 5. Plaintiffs' action is time-barred as it is filed outside of the time permitted by the
14 applicable Statute of Limitations, and same is pleaded in full bar of any liability as to
15 Defendants.

16 **Sixth Defense**

17 6. Plaintiffs' action is barred by the statute of repose.

18 **Seventh Defense**

19 7. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the
20 Complaint, the same were caused by the negligence or fault of the Plaintiffs and Plaintiffs'
21 damages, if any, are barred or reduced by the doctrines of comparative fault and contributory
22 negligence and by the failure to mitigate damages.

23 **Eighth Defense**

24 8. The proximate cause of the loss complained of by Plaintiffs are not due to any acts or
25 omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the
26 part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not
27 liable in any way.

28

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Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiffs were not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiffs.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a “learned intermediary” in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiffs’ treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiffs were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiffs’ causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiffs was prepared in accordance with the applicable

1 standard of care.

2 **Sixteenth Defense**

3 16. If Plaintiffs sustained any injuries or incurred any losses or damages as alleged in the
4 Complaint, the same were caused by the unforeseeable alteration, change, improper handling,
5 abnormal use, or other unforeseeable misuse of Celebrex® by persons other than Defendants or
6 persons acting on its behalf after the product left the control of Defendants.

7 **Seventeenth Defense**

8 17. Plaintiffs' alleged damages were not caused by any failure to warn on the part of
9 Defendants.

10 **Eighteenth Defense**

11 18. Plaintiffs' alleged injuries/damages, if any, were the result of preexisting or subsequent
12 conditions unrelated to Celebrex®.

13 **Nineteenth Defense**

14 19. Plaintiffs knew or should have known of any risk associated with Celebrex®; therefore,
15 the doctrine of assumption of the risk bars or diminishes any recovery.

16 **Twentieth Defense**

17 20. Plaintiffs are barred from recovering against Defendants because Plaintiffs' claims are
18 preempted in accordance with the Supremacy Clause of the United States Constitution and by
19 the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

20 **Twenty-first Defense**

21 21. Plaintiffs' claims are barred in whole or in part under the applicable state law because
22 the subject pharmaceutical product at issue was subject to and received pre-market approval by
23 the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

24 **Twenty-second Defense**

25 22. The manufacture, distribution and sale of the pharmaceutical product referred to in
26 Plaintiffs' Complaint were at all times in compliance with all federal regulations and statutes,
27 and Plaintiffs' causes of action are preempted.

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Twenty-third Defense

23. Plaintiffs' claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiffs' claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiffs' claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiffs' claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiffs' claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiffs' claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiffs are seeking punitive damages, Plaintiffs failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to

1 procedural due process under the Fourteenth Amendment of the United States Constitution and
2 the Constitution of the States of California and Florida, and would additionally violate
3 Defendants' right to substantive due process under the Fourteenth Amendment of the United
4 States Constitution.

5 **Thirty-first Defense**

6 31. Plaintiffs' claims for punitive damages are barred, in whole or in part, by the Fifth and
7 Fourteenth Amendments to the United States Constitution.

8 **Thirty-second Defense**

9 32. The imposition of punitive damages in this case would violate the First Amendment to
10 the United States Constitution.

11 **Thirty-third Defense**

12 33. Plaintiffs' punitive damage claims are preempted by federal law.

13 **Thirty-fourth Defense**

14 34. In the event that reliance was placed upon Defendants' nonconformance to an express
15 representation, this action is barred as there was no reliance upon representations, if any, of
16 Defendants.

17 **Thirty-fifth Defense**

18 35. Plaintiffs failed to provide Defendants with timely notice of any alleged
19 nonconformance to any express representation.

20 **Thirty-sixth Defense**

21 36. To the extent that Plaintiffs' claims are based on a theory providing for liability without
22 proof of causation, the claims violate Defendants' rights under the United States Constitution.

23 **Thirty-seventh Defense**

24 37. Plaintiffs' claims are barred, in whole or in part, because the advertisements, if any, and
25 labeling with respect to the subject pharmaceutical products were not false or misleading and,
26 therefore, constitute protected commercial speech under the applicable provisions of the United
27 States Constitution.

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Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Thirty-eighth Defense

38. To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitution of the States of California and Florida. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiffs; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiffs and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and

1 instructions with respect to the product's use in the package insert and other literature, and
2 conformed to the generally recognized, reasonably available, and reliable state of the
3 knowledge at the time the product was marketed.

4 **Fortieth Defense**

5 40. The claims asserted in the Complaint are barred because Celebrex® was designed,
6 tested, manufactured and labeled in accordance with the state-of-the-art industry standards
7 existing at the time of the sale.

8 **Forty-first Defense**

9 41. If Plaintiffs sustained injuries or losses as alleged in the Complaint, upon information
10 and belief, such injuries and losses were caused by the actions of persons not having real or
11 apparent authority to take said actions on behalf of Defendants and over whom Defendants had
12 no control and for whom Defendants may not be held accountable.

13 **Forty-second Defense**

14 42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
15 was not unreasonably dangerous or defective, was suitable for the purpose for which it was
16 intended, and was distributed with adequate and sufficient warnings.

17 **Forty-third Defense**

18 43. Plaintiffs' claims are barred, in whole or in part, by the equitable doctrines of laches,
19 waiver, and/or estoppel.

20 **Forty-fourth Defense**

21 44. Plaintiffs' claims are barred because Plaintiffs' injuries, if any, were the result of the
22 pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or
23 illnesses, subsequent medical conditions or natural courses of conditions of Plaintiffs, and were
24 independent of or far removed from Defendants' conduct.

25 **Forty-fifth Defense**

26 45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex®
27 did not proximately cause injuries or damages to Plaintiffs.

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Gordon & Rees, LLP
275 Battery Street, Suite 2000
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Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiffs did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiffs would have taken Celebrex® even if the product labeling contained the information that Plaintiffs contend should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiffs' damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiffs' alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiffs.

Fifty-second Defense

52. Plaintiffs' claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug

Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiffs’ claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA’s implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiffs’ claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiffs’ misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiffs were proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiffs’ recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiffs seek punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive

1 damages is also barred under California Civil Code § 3294(b).

2 **Fifty-eighth Defense**

3 58. Plaintiffs' fraud-based claims, if any, are not stated with particularity as required by
4 Rule 1.120 of the Florida Rules of Civil Procedure.

5 **Fifty-ninth Defense**

6 59. Plaintiffs' claims are barred because Celebrex® was designed, manufactured, and
7 marketed in accordance with the state of the art at the time of manufacture per section
8 768.1257, Florida Statutes.

9 **Sixtieth Defense**

10 60. Celebrex® is not defective or unreasonably dangerous, and Defendants are not liable
11 because, at the time of sale or distribution of the Celebrex® alleged to have been used by
12 Plaintiffs, Defendants had complied with applicable regulations of the federal Food & Drug
13 Administration and are entitled to application of section 768.1256, Florida Statutes.

14 **Sixty-first Defense**

15 61. Plaintiffs' injuries and damages, if any, were proximately caused by the negligence or
16 fault of Plaintiff, or persons or parties whose identities are unknown at this time, and such
17 comparative negligence or fault is sufficient to proportionately reduce or bar Plaintiffs'
18 recovery. Thus, Defendants are entitled to have their liability to the Plaintiffs, if any, reduced
19 as a result of the negligence or fault of said persons or entities, pursuant to the provisions of
20 section 768.81, Florida Statutes. To the extent any recovery is permitted in this case, pursuant
21 to sections 768.31 and 768.81, Florida Statutes, judgment must be entered on the basis of
22 Defendants' percentage of fault, taking into account the percentage of fault attributable to all
23 other persons, whether or not a party hereto, and not on the basis of joint and several liability.
24 The persons or entities referred to in this paragraph that are presently unknown to Defendants
25 will be identified in a timely manner consistent with *Nash v. Wells Fargo*, 678 So. 2d 1262
26 (Fla. 1996).

27 **Sixty-second Defense**

28 62. Plaintiffs fail to state a claim for violation of The Florida Deceptive and Unfair Trade

Practices Act ("FDUTPA").

Sixty-third Defense

63. FDUTPA does not apply to claims for personal injuries, and, accordingly, Plaintiffs' FDUTPA claim is improper and should be dismissed.

Sixty-fourth Defense

64. The acts or practices of which Plaintiffs complain were and are required or specifically permitted by federal or state law. Therefore, Plaintiffs' FDUTPA claim is barred, fails to state a claim, and should be dismissed with prejudice.

Sixty-fifth Defense

65. Plaintiffs lack standing because the answering Defendants did not engage in deceptive conduct with regard to Plaintiff or otherwise.

Sixty-sixth Defense

66. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiffs' claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiffs take nothing from Defendants by reason of the Complaint;
2. That the Complaint be dismissed;
3. That Defendants be awarded their costs for this lawsuit;
4. That the trier of fact determine what percentage of the combined fault or other liability of all persons whose fault or other liability proximately caused Plaintiffs' alleged injuries, losses or damages is attributable to each person;
5. That any judgment for damages against Defendants in favor of Plaintiffs be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiffs' injuries and damages; and
6. That Defendants have such other and further relief as the Court deems appropriate.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

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May 30, 2008

GORDON & REES LLP

By: : /s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

May 30, 2008

TUCKER ELLIS & WEST LLP

By: : /s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants
PFIZER INC., PHARMACIA
CORPORATION, AND G.D. SEARLE
LLC

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

May 30, 2008

GORDON & REES LLP

By: : _____/s/
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

May 30, 2008

TUCKER ELLIS & WEST LLP

By: : _____/s/
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants
PFIZER INC., PHARMACIA
CORPORATION, AND G.D. SEARLE
LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111